K032082
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JUL 30 2003

510(k) Summary for the AURORA Magnetic Resonance Diagnostic Device

(per 21CFR807.92)

1. SPONSOR

Aurora Imaging Technology, Inc.
39 High Street
North Andover, MA 01845

Contact Person: Vera Zhang
Telephone: 978-975-7530 x 4322

Date Prepared: July 3, 2003

2. DEVICE NAME

Proprietary Name: AURORA
Common/Usual Name: Magnetic resonance imaging device
Classification Name: Magnetic resonance diagnostic device

3. PREDICATE DEVICES

AURORA MRI system (K012154)

4. DEVICE DESCRIPTION

The modified AURORA is identical to the AURORA breast imaging system cleared by FDA through K012154 except that the magnet is ramped to 1.5 T and the RF system and spectrometer have been changed to operate at the higher frequencies required for 1.5 T operation.

5. INTENDED USE

The AURORA MRI system is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structure of the extremities (breast tissue, axilla, and chest wall local to the breast). The images produced by the MR system reflect the spatial distribution of protons (hydrogen

nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The AURORA is a dedicated breast MRI system intended to be used as an adjunct to conventional breast screening methods.

- Anatomical region: Breast tissue, axilla, and chest wall local to the breast
- Nucleus excited: Proton
- Diagnostic uses: 2D, 3D T1- / T2-weighted imaging
  TI, T2, proton density measurements
  Image processing
- Imaging capabilities: 2D Spin Echo (SE)
  2D/3D Gradient Echo (GRE)
  Fat Suppression
- Imaging processing: Image Subtraction
  Image Filtering

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Aurora Imaging Technology, Inc. makes a claim of substantial equivalence of the modified AURORA to the predicate AURORA (K012154) based on similarities in intended use, design, and technological and operational characteristics. Both are indicated for magnetic resonance imaging of the breast. Both systems use the same hardware and software except that the magnet is ramped to 1.5 T for the upgraded AURORA instead of 0.5 T for the predicate AURORA, and the RF system and spectrometer have been modified to increase their frequency of operation.

7. TESTING

Testing was performed to validate the performance of the AURORA operating at 1.5 T. Testing included measurement of acoustic noise, Specific Absorption Rate, slice thickness, SNR and image uniformity according to NEMA standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2003

Aurora Imaging Technology, Inc.
c/o Mr. James R. Veale
Vice President, Strategic
and Technical Assistance
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K032082
Trade/Device Name: AURORA MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: July 3, 2003
Received: July 7, 2003

Dear Mr. Veale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032082

Device Name: **AURORA**

Indications for Use:

The AURORA MRI system is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structure of the extremities (breast tissue, axilla, and chest wall local to the breast). The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

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  Fat Suppression
- Imaging processing: Image Subtraction
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032082

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)